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10/527,390	10/17/2005	Franz Freudenthal	STERN25.001APC	8620

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EXAMINER

SIMPSON, SARAH A

ART UNIT	PAPER NUMBER
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4148

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/527,390	Applicant(s) FREUDENTHAL ET AL.	
	Examiner SARAH A. SIMPSON	Art Unit 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to application no. 10/527390 filed 10/17/2005.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 102 42 444.6, filed on 9/11/2002.

Claim Objections

2. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claim 15** recites the limitation "the tubular element is made in one piece with the second collecting basket" in which there has been no previous claim reciting a second collecting basket. There is insufficient antecedent basis for this limitation in the claim.

5. **Claims 24 & 25** recite the limitation "the cuts in the slotted tube" in which there has been no previous claim reciting the cuts. There is insufficient antecedent basis for this limitation in the claim.

6. **Claim 30** recites the limitation "the second collecting basket has a self-opening partial area" in which there has been no previous claim reciting a second collecting basket. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. **Claims 1 – 3, 18 & 30** are rejected under 35 U.S.C. 102(b) as being anticipated by **Broome et al. (US 2002/0082639 A1)**.

Regarding claim 1, Broome et al. disclose an extraction device for extracting objects, in particular clots, foreign bodies, etc., from cavities in a human or animal body, with first (282) and second (308) compressible and expandable collecting baskets between which the object can be captured (fig. 21), said collecting baskets being mutually displaceable and being able to be drawn one into the other, wherein at least one collecting basket (282) is umbrella-like in the expanded state and is designed with flexible wire-like adjustment elements for deliberately changing the shape and/or position of the collecting basket so that the object can be captured in the latter and can be drawn into the other collecting basket (fig. 21; [0075]).

Regarding claim 2, Broome et al. disclose the extraction device as claimed in claim 1, wherein the umbrella-like collecting basket (282) opens in the direction toward the other collecting basket (308) or in the direction away from the other collecting basket (fig. 21).

Regarding claim 3, Broome et al. disclose the extraction device as claimed in claim 1, wherein both collecting baskets (282, 308) are provided with at least one adjustment element (32, 284) for deliberately adjusting the shape and/or position of the collecting baskets ([0075], lines 5-13).

Regarding claim 18, Broome et al. disclose the extraction device as claimed in claim 1, wherein a guide cannula (32) is provided which is secured on the distal end of

the first collecting basket ((282); [0038]; [0075]; it is inherent that the basket (282) is fixedly secured to the guidewire (32) similar to the collecting basket (22)).

Regarding claim 30, Broom et al. disclose the extraction device as claimed in claim 1, wherein at least the second collecting basket has a self-opening partial area (306) and a self-closing partial area (308), which self-closing partial area can be opened deliberately by at least one adjustment element ((283); [0073]; [0074]; wherein the self closing portion is retracted within inner tube or adjustment element and assumes a collapsed position).

9. **Claims 4 – 17, 20, 22 – 29, & 32** are rejected under 35 U.S.C. 102(e) as being anticipated by **Kusleika et al. (US 2002/0169474 A1)**.

Regarding claim 4, Kusleika et al. disclose an extraction device (250) for extracting objects, in particular clots, foreign bodies, etc., from cavities in a human or animal body, with at least one compressible and expandable collecting basket (270) having a distal end (284) and a proximal end (286), wherein at least one wire-like flexible adjustment element (290) is secured at the distal and/or proximal end (286) in such a way that the at least one collecting basket (270) can be deliberately oriented by the latter and changed in shape ([0006]; figs. 1-2).

Regarding claim 5, Kusleika et al. disclose the extraction device as claimed in claim 3, wherein the at least one adjustment element (290) has one or more thin wires ([0015], lines 1-3).

Regarding claim 6, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the at least one adjustment element (290) is arranged on the outside

and/or inside of the at least one collecting basket (270), in particular at least partially integrated into the circumferential surface of the collecting basket and/or laced into this ([0015]).

Regarding claim 7, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the at least one adjustment element (290) protrudes beyond the outstretched length of the at least one collecting basket (270) and is arranged to be actuated in particular from the proximal end (286), in particular to be actuated via a handgrip ([0017]; wherein the handgrip is the external catheter).

Regarding claim 8, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein, with an adjustment element (290) provided at the proximal end (286) of the collecting basket (270), the latter has an asymmetrical design, in particular lengthened on one side in the area of attachment of the adjustment element (290), and/or is provided with a hook-shaped element for engagement of an adjustment and/or guide element ([0011], lines 8-12; wherein the collecting basket is capable of being any suitable shape, including an asymmetrical design).

Regarding claim 9, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the adjustment element or elements (290) are secured on the collecting basket (270) in a branched-out configuration and are brought together in groups proximally (figs. 1-2; [0015]).

Regarding claim 10, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the at least one adjustment element (290) is in one piece with the collecting basket ((270); [0015]).

Regarding claim 11, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the distance between the distal end (284) of the collecting basket (270) and at least one proximal point of attachment or point of emergence of the at least one adjustment element (290) is constant for different designs of the collecting basket ([0011]; wherein the baskets may be any suitable shape; therefore, capable of having a constant distance between distal end and proximal point of attachment).

Regarding claim 12, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the proximal end (286) of the at least one collecting basket (270) can be fixed or is fixed in a tubular element, in particular a catheter (C), and the adjustment element or elements (290) are guided or can be guided through the tubular element (figs. 2A-2B).

Regarding claim 13, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the at least one collecting basket (270) is designed so that it shortens in its longitudinal direction upon widening and lengthens when its cross section is reduced, and in particular can be expanded to a diameter, greater than the diameter of the cavity to be cleared, for partial widening of the cavity ([0011], lines 1-8; figs. 2A-2B).

Regarding claim 14, Kusleika et al. disclose the extraction device as claimed in claim 12, wherein a sleeve element (266, 274) for strengthening the connection between tubular element (C) and collecting basket (270) is provided at the proximal end (286) of the at least one collecting basket ((270); figs. 2A-2B).

Regarding claim 15, Kusleika et al. disclose the extraction device as claimed in claim 12, wherein the tubular element made in one piece with a second collecting

basket (340) provided with cuts to permit expansion and compression (figs; 3-5; [0021]; [0024], lines 6-8; wherein the basket 320 is directly analogous to the basket 270 and the cuts are between the wires of second basket 340, which is formed of a metallic tubular braid).

Regarding claim 16, Kusleika et al. disclose the extraction device as claimed in claim 11, wherein reducing elements (290) arranged transversely with respect to the longitudinal extent of the at least one collecting basket are provided, in particular in the area of the proximal (286) and/or distal ends of the collecting basket (270) and/or in the area of the at least one proximal point of attachment or point of emergence of the at least one adjustment element, and the reducing elements are in particular nooses ([0015]; wherein the tethers may be intertwined with the wires of the metal fabric to be kept in place and will extend along the proximal lip of the basket, acting as drawstrings or nooses, drawing the end of the basket radially inwardly toward the guidewire).

Regarding claim 17, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the adjustment element or elements (290) are fixed or movably guided in at least one tubular element (C) in particular a catheter ([0018]).

Regarding claim 20, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein a channel element (C) is provided which has an internal diameter such that the at least one collecting basket (270), a guide cannula (266) and/or tubular elements (268) and the adjustment element or elements (290) can be guided through it (fig. 2A).

Regarding claim 22, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein at least one collecting basket (270) is made of a braided fabric and/or woven fabric and/or scrim, in particular a wire braid and/or woven wire fabric and/or wire scrim and/or at least one collecting basket is composed of a tube slotted along at least part of its length and/or is provided with a coating ([0009], lines 1-4; wherein the basket is formed of a metal fabric and may be braided).

Regarding claim 23, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the at least one adjustment element (290) is formed from a part of a braided fabric, woven fabric, scrim, or a slotted tube ([0015]).

Regarding claim 24, Kuleika et al. disclose the extraction device as claimed in claim 22, wherein the cuts in the slotted tube are made in such a way as to afford the maximum ratio of shortening and widening upon expansion of the collecting basket ([0024]; [0025]; wherein the metallic tubular braid, cuts in the tube, is adapted to be collapsed to lay generally along the outer surface of the guidewire. When collapsed, the cuts are closed; therefore, it is inherent that the maximum shortening and widening ratio is used).

Regarding claim 25, Kuleika et al. disclose the extraction device as claimed in claim 24, wherein the cut or cuts in the slotted tube are made long in comparison to the lengthwise extent of the collecting basket (fig. 5; wherein the cuts toward the proximal end of the second collecting basket (340) are longer in comparison to the cuts near the distal end).

Regarding claim 26, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein the at least one collecting basket (270) is made of a biocompatible material, in particular a metal or a metal alloy ([0009], lines 1-2), in particular a stainless steel or nitinol and/or the material of the at least one collecting basket (270) is coated with a material, in particular a biocompatible surface coating, heparin, a carbonization of nitinol, a nanotechnological coating, radiopaque particles, a coating releasing active substance, an in particular microporous biotechnological or other coating ([0013], lines 13-15).

Regarding claim 27, Kusleika et al. disclose extraction device as claimed in claim 4, wherein partial areas of the at least one collecting basket (270) are made of material of different diameter, in particular an expandable partial area (x) of the at least one collecting basket (270) is made of a material with a thinner cross section or has a braided fabric or scrim or woven fabric with filaments of different diameter ([0013], lines 1-3; wherein the dimensions of the metal fabric used to make the collecting baskets may be varied; therefore, capable of having materially different diameters).

Regarding claim 28, Kusleika et al. disclose the extraction device as claimed in claim 27, wherein the material of the at least one collecting basket (270) in at least one partial area is chemically and/or mechanically treated, in particular etched, electrolytically polished, microground or otherwise treated ([0013], lines 13-15).

Regarding claim 29, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein a guide wire (260') and/or inner mandrel is provided along which the at

Art Unit: 4148

least one collecting basket (270) can be displaced and/or can be inserted into the cavity ([0018]; figs. 2A-2B).

Regarding claim 32, Kusleika et al. disclose the extraction device as claimed in claim 4, wherein a means ([006]) is provided for cutting or separating objects, in particular a wire provided with a material thickening, in particular a ball, a helical portion, a noose-shaped portion, a combination of these or some other type of material thickening, which wire (260') can be or is arranged so as to be movable inside the collecting basket (270), and/or a balloon catheter provided with a stent or such like element ([0006]; [0018]).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Broome et al. (US 2002/0082639 A1)**.

Regarding claim 19, Broome et al. disclose the extraction device as claimed in claim 18, but fail to disclose wherein the guide cannula and/or the tubular element or elements is/are made of a flexible material, in particular a metal, a metal alloy, a plastic or another flexible material or combination of materials, in particular of nitinol.

However, Broome et al. teach the wire mesh of the extraction device is made of nitinol or similar material having sufficient elasticity or resilience ([0040]).

14. Given the teachings of Broome et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the extraction device with a nitinol guide cannula and/or tubular element. Doing so would provide a strong and flexible guide cannula.

15. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kusleika et al. (US 2002/0169474 A1)**.

Regarding claim 21, Kusleika et al. disclose the extraction device as claimed in claim 20, but fail to disclose wherein the channel element is made of a stable and at least partially flexible material, in particular of a plastic, metal, a metal alloy, in particular nitinol, in particular a thin-walled nitinol tube.

However, Kusleika et al. teach metal fabric formed of a material which is both resilient and which can be heat treated to substantially set a desired shape. Such materials include metal alloys and nitinol ([0071]).

16. Given the teachings of Kusleika et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the channel element with a thin-walled nitinol tube. Doing so would provide a strong and flexible channel.

17. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kusleika et al. (US 2002/0169474 A1)** in view of **Bates et al. (US 6,280,451)**.

Regarding claim 31, Kusleika et al. disclose the extraction device as claimed in claim 4, but fail to disclose wherein the extraction device can be used in conjunction with an endoscope with or without provision of a channel element.

However, Bates et al. teach medical retrieval baskets generally are used to retrieve biological and foreign material from the body including stones. Such baskets may be used through an endoscope or a laparoscope (column 1, lines 19-22).

18. Given the teachings of Bates et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the extraction device with the use of an endoscope. Doing so would improve ability and accuracy of guiding the device to the target site.

19. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kusleika et al. (US 2002/0169474 A1)** in view of **Broome et al. (US 2002/0082639 A1)**.

Regarding claim 32, Kusleika et al. disclose the extraction device as claimed in claim 4, but fail to disclose wherein a suction means is provided for suctioning of objects or parts of objects, in particular a cannula or such like tubular means which can be guided into the area of the collecting basket and can be acted on by a partial vacuum.

However, Broome et al. teach a extraction device with a suction means to remove debris and severed pieces ([0007]).

20. Given the teachings of Broome et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the extraction device with a suction means. Doing so would remove all of the debris or unwanted objects from cavities, without removing the baskets. Therefore, multiple objects could be removed from the cavity without removing the baskets.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitation of the applicant's claimed and disclosed invention: **Adams et al. (US 2002/0004667 A1)**, **White et al. (US 2002/0068944 A1)**, **Mazzocchi et al. (US 2002/0072765 A1)**, **Demarais et al. (US 2002/0151906 A1)**, **White et al. (US 2005/0216031 A1)**, & **Martinez et al. (US 2006/0030877 A1)**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 4148
25 April 2008
/Terrell L McKinnon/ Supervisory Patent Examiner, Art Unit 4148